IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Henot et al.

Art Unit: 1614

Application No: 10/561,175

Examiner: S. X. Wen

Confirmation No: 1959

Filed: February 16, 2006

Atty. Docket No: 37998-237505

Customer No:
26694
PATENT TRADEMARK OFFICE

For: EPITOPE COMPOSITION FOR SUBLINGUAL, BUCCAL OR ENTERIC ADMINISTRATION PREPARED BY HYDROLYSIS OF ANTIGENIC STRUCTURES WITH CHYMOTRYPSIN

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Restriction Requirement as set forth in the Office Action of January 24, 2007, Applicants elect Group I, with **traverse**. Group I contains claims 15-23 and 27-29, drawn to a pharmaceutical composition comprising substances obtainable by hydrolysis with chymotrypsin or any other protease of an antigenic structure.

The Restriction Requirement alleged that unity of invention does not exist for Groups I-III, citing U.S. Patent 6,312,711 to Duchateau et al (Duchateau). Specifically, the Restriction Requirement states that Duchateau "teaches the oral administration of the pharmaceutical composition which includes sublingual, buccal, and enteric formulations recited in the present claims" (Office Action, page 3, para 4). Applicants respectfully disagree. Contrary to the position set forth by the Office, the oral administration disclosed in Duchateau does not include the sublingual, buccal, and enteric administration of the present claims.

The oral administration disclosed in Duchateau teaches only that the pharmaceutical formulation enters the body through the mouth. Duchateau does not disclose where in the body the pharmaceutical formulation is absorbed. Most orally administered pharmaceutical formulations are absorbed in the stomach. In contrast, the sublingual and buccal administration recited in the present

claims allow absorption in the mouth mucosa. See, *e.g.*, Application Specification, page 5. Enteric administration involves a special formulation that protects the active ingredient from conditions in the stomach, and is made for absorption in the ileum, duodenum, or jejunum (id). As disclosed in the specification, an enteric formulation can be a suppository (id). Thus an enteric formulation in accordance with the present claims need not be orally administered.

As Duchateau does not teach the technical features of the present claims, Groups I-III teach a single inventive concept under PCT Rule 13.1 and restriction is not proper. However, in order to be fully responsive to the Restriction Requirement, Applicants elect Group I, with traverse. Regarding the species election for a specific disease, Applicants elect allergic reaction (claim 15) with traverse.

The Action further requires the election of an ultimate disease as recited in the specification on page 3. Since it appears that there is no specified ultimate disease on page 3 of the specification for the allergic reaction recited in claim 15, it is submitted that an election regarding an ultimate disease is not required. If the Examiner holds different view, Applicants respectfully request a more detailed explanation of the election requirement.

Regarding the election of a specific substance (claim 22), Applicants elect, with traverse, nucleoside triphophates. Regarding the election of a specific antigenic structure (claim 23), Applicants elect grass allergens, with traverse.

All claims of group 1 (15-23 and 27-29) read on the elected species.

The Office is authorized to charge deposit account no. 22-0261 in the amount of $525 for the extension fees. If any additional fees are due, the Office is further authorized to charge deposit account no. 22-0261 with notification sent to the undersigned.

Dated: May 18, 2007

Respectfully submitted,

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